IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *City of Cleveland, et al. v. Purdue Pharma L.P.*, Case No. 18-OP-45132; *County of Cuyahoga, et al. v. Purdue Pharma L.P., et al.*, Case No. 17-OP-45004; *County of Summit, et al. v. Purdue Pharma, L.P. et al.*, Case No. 18-OP-45090	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

MANUFACTURER DEFENDANTS' JOINT OBJECTIONS TO THE SPECIAL MASTER'S DISCOVERY RULINGS NOS. 2 AND 3

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Pursuant to Fed. R. Civ. P. 53 and this Court's Orders, the Manufacturer Defendants respectfully request modification of Discovery Rulings Nos. 2 and 3 as set forth in Appendix A. *See* Dkt. 693, Discovery Ruling No. 2 (Ex. 1); Dkt. 762, Discovery Ruling No. 3 (Ex. 2).

INTRODUCTION

Discovery Order No. 2 was entered without a hearing and disproportionately requires each of the Manufacturer Defendants to collect and review two decades' worth of documents related to opioids, regardless of whether those opioids are the subject of allegations in the Track One complaints. The order calls for production of documents created ***22 years*** before the filing of the Track One complaints, a period nearly ***six times longer*** than the federal RICO statute of limitations. Worse, it requires such production to be completed in a matter of weeks, before the close of fact discovery on August 31, which prevents Manufacturers from meaningfully preparing witnesses for deposition. Plaintiffs have seized upon the disproportionate burden of this discovery, refusing to compromise on scope and making clear their intent to use the Special Master's ruling to insist on multiple depositions of witnesses whose full custodial files simply cannot be produced by August 31 under the Rulings—a result the Court has indicated would be duplicative and burdensome. Combined with the aggressive trial schedule currently in place, this imposes a massive burden on Defendants and will deprive Defendants of a meaningful opportunity to defend themselves in this litigation. This is clear error, as it will result in a basic denial of due process and violates the proportionality and relevance requirements of Fed. R. Civ. P. 26.

The unprecedented breadth of the discovery ordered—without analyzing the burden imposed on each Manufacturer Defendant based on their unique circumstances—is also wholly incompatible with the Court's current trial date. At best, the Manufacturer Defendants have concluded—as supported by declarations that go completely unaddressed by Plaintiffs or the Special Master—that the ordered discovery would take six months or more to complete. Of course,

that estimate does not take into consideration that Defendants need time to prepare witnesses based on the ordered production of decades' worth of documents, once they are able to be produced. In sum, any realistic possibility of expeditious progress toward trial—or settlement—simply cannot be accomplished at the same time defendants are being compelled, as but one example, to locate and produce millions of documents dating back to the 1990s—even where the Track One complaints are entirely silent about conduct by the majority of parties during that time.

Despite its recent but insufficient modification by the Special Master, Discovery Ruling No. 2 must be further modified to focus on genuinely relevant productions and testimony, rather than permitting burdensome and disproportionate fishing expeditions into virtually every opioid-related document in a defendant's possession. The result of the Rulings, if left intact, will ensure that the Court-ordered schedule will require drastic modifications and will further deny the Manufacturing Defendants basic due process to adequately mount a defense to Plaintiffs' claims.

BACKGROUND

In late April, Plaintiffs served Requests for Production seeking wide-ranging discovery on nearly all of Manufacturer Defendants' opioid medications over a more than 30-year period. Plaintiffs' requests were wholly untethered to the allegations in their Track One Complaints and—as Defendants explained to the Special Master—were impossible to comply with during the short time period allotted for fact discovery in the Track One cases. Accordingly, Defendants objected but began to devote significant resources to begin preparing extensive, rolling productions designed to provide Plaintiffs the discovery they needed on the schedule on which they had insisted. Defendants likewise attempted to negotiate reasonable compromises with Plaintiffs as directed by the Special Master. Plaintiffs rebuffed such efforts and moved to compel.

On June 30, without permitting a hearing, the Special Master entered Discovery Ruling No. 2, which dramatically expanded the scope of discovery. ***First***, it required production of

documents "related to all opioid products that are or ever were classified as Schedule II"—regardless of whether there were any substantive allegations at all about such medications. *See* Ruling No. 2 at 3. ***Second***, it required the production of certain data dating back to 1996 and other documents regarding branded opioids dating one year prior to each product's launch (or one year prior to being sold in the case of generics). *Id.* at 8-11. ***Third***, contrary to the plain text of CMO No. 1, the Special Master required the production of nearly ***all*** prior productions—regardless of whether they were made to governmental entities, whether they were relevant to the claims against that particular Defendant, or when they had been made. *Id.* at 5-8. It also required the production of certain documents in six states beyond Ohio. *See id.* at 3-5. While the burdens differed for each Defendant given their specific circumstances, the Ruling failed to consider these distinctions and improperly treated all Manufacturer Defendants as one.

Because it was impossible to collect, review and produce documents before August 31 about all opioids over decades of time, much less in time for depositions to occur, the Manufacturer Defendants requested reconsideration. The Manufacturer Defendants' briefing explained, defendant-by-defendant, the practical problems associated with Discovery Ruling No. 2 that rendered the order impossible to comply with, and included supporting affidavits. *See* Ex. 3, July 11, 2018 Letter Brief; Ex. 4, July 17, 2018 Reply Letter Brief.

Without a hearing and without addressing Defendant-specific issues, Special Master Cohen entered Discovery Ruling No. 3, which did not address the key issues raised by Defendants. For some discovery, the amended Ruling limited the geographic scope. *Id.* While this provides ***some*** relief to ***some*** Defendants, it does not affect the burdens of several at all (in fact, some Defendants had already agreed to nationwide discovery based on company-specific circumstances). Left unchanged were crucial rulings regarding time period, product scope, and prior productions, which

render the Rulings impossible to comply with on the current schedule, disproportionately burden Defendants, and severely prejudice Defendants' ability to defend themselves. *Id.* Accordingly, the Manufacturer Defendants respectfully request that the Court modify the Rulings. *See* Proposals in Appendix A.

LEGAL STANDARD

The Special Master's conclusions of law and factual findings are reviewed *de novo*, and procedural matters for abuse of discretion. *See* Fed. R. Civ. P. 53(f)(3)-(5); Dkt. 69 at 4-5.

ARGUMENT

I. THE MANUFACTURER DEFENDANTS' OPPORTUNITY TO PRESENT THEIR DEFENSES IS SEVERELY PREJUDICED BY THE RULINGS.

Under settled law, discovery has reasonable limits. Plaintiffs may obtain discovery only when it is both relevant to their claims ***and*** proportional to the needs of the case. *See In re: Takata Airbag Prod. Liab. Litig.*, 2016 WL 1460143, at *2 (S.D. Fla. Mar. 1, 2016) (explaining that "a party is not entitled to receive every piece of relevant information"). Yet the Rulings broaden discovery to products, time periods and prior productions such that it is nearly limitless and would be impossible to comply with by August 31 or even within many months. These problems are compounded because depositions are now occurring. Absent modification, Defendants are forced to prepare witnesses to testify regarding decades of information and products about which there are no allegations in Plaintiffs' Complaints. Requiring the production of witnesses before Defendants can review the documents violates due process. *See Simon v. Craft*, 182 U.S. 427, 436 (1901) ("The essential elements of due process of law are notice and opportunity to defend.").

Similarly, the Rulings impose an undue and unrealistic burden on Defendants to seek out document productions in "*any* prior litigation that involved the marketing or distribution of opioids." *See* Ruling No. 2 at 6. This ruling ignores that CMO No. 1 limited such productions to

those "by federal (including Congressional), state, or local government entities." *See* Dkt. 232 at ¶ 9(k)(ii). The Rulings' interpretation is contrary to the plain text and would require Defendants to search for, collect, and produce an enormous number of prior productions without any limitation by date and hardly any subject matter restriction. Even if they could gather and produce them in time, Defendants would have no meaningful opportunity to review these prior productions ahead of depositions such that they could properly defend themselves.

More fundamentally, the Rulings did not properly consider and give due weight to each Defendant's particular circumstances.[1] Ruling No. 2 imposes the same uniform time period on all defendants dating back to 22 years before the filing of the complaints. For example, it orders all of "the manufacturer defendants" as an undifferentiated group to "produce transactional data" and "Suspicious Order Reports" dating back to the same "cut-off date of January 1, 1996." Ruling No. 2 at 10-11. Ruling No. 2's "one year prior to the launch date" rule is also uniform: the same rule not only applies to all defendants, but also to all products sold by all defendants, even generic products for which the "one year prior to launch" rule makes little sense. As explained below in Section II, this "one size fits all" rule is inherently not proportional to each Manufacturer Defendant under Rule 26. The Rulings reflect no such consideration and instead prevent the Manufacturer Defendants from fairly defending themselves and result in severe prejudice.

II. EACH MANUFACTURER DEFENDANT'S PROPOSED MODIFICATIONS SHOULD BE ACCEPTED.

Allergan Finance, LLC ("Allergan"). The only opioid with respect to which Plaintiffs have made any substantive allegations of wrongdoing by Allergan is Kadian®. The only other

[1] Contrary to the amended Ruling, the Manufacturer Defendants did not "unanimously implore the Special Master to limit further the geographic scope of discovery." *See* Ruling No. 3 at 2-3; Exs. 3 and 4, July 11, 2018 and July 17, 2018 Letter Briefing. Rather, the burden on Allergan and certain other Manufacturer Defendants is not reduced at all by the reduction in geographic scope, as they had already agreed to provide nationwide discovery regardless.

Allergan opioid mentioned in the Complaints is Norco®. Yet, Plaintiffs have sought discovery regarding every opioid ever sold by Allergan or its predecessors over two decades, including generics—even though Allergan sold its generics business to another defendant group, Teva, which not only owns the products but the associated documents and data. *See* Ex. 5, July 26, 2015 Agreement. This sale included not only the opioids themselves but also the "Actavis" entities—including those named as Defendants—that manufacture and sell all generics as well as the liability (if any) for them. *See* Ex. 6, January 31, 2018 Agreement at § 4. The vast bulk of the related documents, data, and personnel went to Teva, which is the proper source for discovery regarding these products and has indicated it intends to produce such discovery.[2] Nonetheless, the Special Master swept Allergan into the Rulings for purposes of "all opioids." As a result, a literal reading would require Allergan to engage in duplicative discovery as well as to collect documents and data to determine what scant information it may still possess. Such an effort would take months or more, is duplicative in most respects of discovery demanded of Teva, and is wholly disproportional.

The temporal scope under the Rulings compounds this issue. For example, although Allergan did not acquire Kadian® until 2008, the Rulings would require it to collect, search for and review documents dating back to "one year prior to the launch date of the opioid product in question," "regardless of when the defendant acquired rights to the drug." *See* Ruling No. 2 at 10 & n.5. Because Kadian was launched by another company in 1997, Allergan would have to search for documents going back ***more than a decade before it even acquired the medication***.

[2] Any request from Plaintiffs for the production of any additional prior productions relating to the generic opioids or suspicious order monitoring (the entities responsible for which were transferred to Teva) are also better suited for Teva and the transferred entities. It is not clear, though, whether there is any dispute between the parties on this point, as Allergan has directed Plaintiffs to Teva and the transferred entities for the provision of such prior productions, and Plaintiffs have not objected. *See* Ex. 7, July 10, 2018 Letter to Plaintiffs.

The Rulings thus impose unrealistic burdens on Allergan with which it cannot comply by August 31—even using best efforts. Plaintiffs have refused any effort to compromise. Instead, they doubled down, demanding the use of more than 14,000 additional search terms that include, among others, myriad terms involving generic opioid products. *See* Ex. 8, Decl. of A. Lee ¶¶ 6-7. To estimate the burden of producing discovery about the generics, Allergan ran those terms across data collected to date. *Id.* ¶ 7. The results would require promotion into the review database of more than 3.7 million documents (and likely many more depending on the date range). *Id.* This would require many tens of thousands of additional attorney hours just for first-level review. *Id.*

Accordingly, Allergan requests a reasonable modification of the Rulings that would require it to expand its production to include Norco® (in addition to Kadian®, with respect to which it has been producing hundreds of thousands of documents). Under this proposed solution, Allergan would, *inter alia*, produce the files of 12 additional custodians as well as 96 additional search terms, and it would ***remove*** the front-end date limitation ***completely***. This would provide Plaintiffs with the discovery they need as to the claims against Allergan in their Complaints.

Mallinckrodt LLC ("Mallinckrodt"). Ruling No. 2 disproportionately impacts Mallinckrodt by imposing a time period for branded *and* generic products stretching back to the 1990s, well over a decade earlier than the earliest allegation in any Track One complaint asserting any actionable conduct by Mallinckrodt. Plaintiffs allege that Mallinckrodt generated demand through false statements to the medical community regarding opioids, but the Track One complaints allege such conduct by Mallinckrodt ***only for two products***: Exalgo (from 2010-14) and Xartemis (from 2014-15). *See* Summit SAC ¶ 228.[3] The Ruling nonetheless requires

[3] In addition to promotion of these two branded opioid products, Plaintiffs allege that Mallinckrodt promoted "opioids generally"—for example, advertising the benefits of therapeutic pain treatment without reference to any specific product, whether branded or generic. Mallinckrodt disputes those allegations but has agreed to provide any such non-product-specific promotional documents, so there is no dispute.

that Mallinckrodt provide discovery of materials dating back to a year before the launch of the ***13 additional Schedule II opioids*** that the complaints list as having been "manufactured" by Mallinckrodt. But all of these products were generics for which Mallinckrodt did ***not*** use sales representatives or otherwise promote. As such, the Ruling is inconsistent with Plaintiffs' theory of the case and falls below the threshold for Rule 26 discovery. Moreover, a mid-1990s cut-off for Mallinckrodt is plainly inconsistent with any statute of limitations. The proposed time period is nearly six times longer than the RICO limitations period and 22 times longer than the limitations period under plaintiffs' Ohio "criminal acts" theory. Documents more than a decade old simply do not bear on the claims against Mallinckrodt.

Moreover, Mallinckrodt's branded opioid business has not existed for several years. Extending discovery for Mallinckrodt back to the 1990s would require time-consuming collection of warehoused hard copy documents. *See* Ex. 9, Decl. of A. O'Connor at ¶¶ 9, 15-18. And, imposing a beginning date in the mid-1990s—15 and 19 years, respectively, before Mallinckrodt ever promoted Exalgo or Xartemis,—would also impose unreasonable burdens on Mallinckrodt's witnesses, including those 30(b)(6) witnesses who would be expected to absorb 30 years of history on the minutiae of the company's operations. *See id.*

A discovery time period of 2008-2017 is more appropriate given Plaintiffs' own allegations regarding Mallinckrodt's use of sales representatives and promotion in the Track One jurisdictions. The reasonableness of a 2008-2017 time period is corroborated by the fact that, as the Track One Complaints repeatedly reference, the DEA conducted an extensive investigation directly concerning Mallinckrodt's opioid diversion controls. In investigating the company's diversion controls, DEA decided that the relevant time period applicable to Mallinckrodt had an

earliest date of 2008—not the mid-1990s. According to Plaintiffs, "The DEA's interpretation is entitled to deference and 'given considerable weight'." Doc #654, Opp. to MTD, p. 83.

Teva Defendants.[4] The Teva Defendants are unable to satisfy Plaintiffs' far-reaching discovery requests before the fact discovery deadline of August 31, much less before depositions are taken. Plaintiffs seek custodial email and database extractions from the Teva Defendants pertaining to virtually every aspect of five separate corporate entities including entities that Teva did not acquire until late 2016 and as to which the vast majority of employees knowledgeable about these companies and their data are no longer employed by the company. That would be burdensome enough, if the scope of discovery encompassed a 12-year period – as Teva had proposed, based upon the facts pled in the Complaints. That 12-year period was already exceedingly long given that the longest statute of limitations potentially applicable to any of Plaintiffs' claims is five years. Yet, under the Rulings, the Teva Defendants now must collect and produce discovery concerning approximately 150 products spanning two decades. While the Teva Defendants had compromised on Plaintiffs' request for discovery of generics (without conceding that Plaintiffs had stated any viable claim as to generics, which they cannot), the combination of the expansion of products and the time frame imposed by the Rulings makes it impossible for the Teva Defendants to comply with Plaintiffs' discovery requests within the current schedule.

The Teva Defendants have made seven document productions in the MDL, amounting to approximately 64,500 documents and more than 850,000 pages. Necessarily, the number of documents and pages that the Teva Defendants collected and reviewed to generate these productions is exponentially greater. To date, the Teva Defendants have collected over 750 gigabytes of email data alone; applying the temporal scope of the Rulings, the Teva Defendants

[4] The "Teva Defendants" include Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.

estimate they will need to review well over three million documents just for custodial email.[5] The Teva Defendants also diligently have been collecting and producing substantial volumes of non-custodial documents and continue to locate and process additional documents produced in prior litigations. Specifically, the Teva Defendants have identified 26 prior productions, spanning approximately 14 years, and are investigating whether productions were made in more than 50 actions filed against the Acquired Actavis Entities. Most of these prior productions, particularly pre-2010 productions, are from databases not currently under the Teva Defendants' control, thereby significantly complicating their ability to locate and process these productions. *See* Ex. 10, Sanchez Decl. Given Plaintiffs' expansive (and growing) discovery requests, and the Rulings as to product scope, temporal scope and prior productions, the Teva Defendants are collecting and producing documents at breakneck speed but are unable to adequately review and digest those documents. The Teva Defendants thus are prejudiced in their ability to effectively prepare their witnesses for depositions, and to defend against Plaintiffs' claims.

Purdue Defendants. The Special Master's vast expansion of discovery is unduly burdensome for Purdue and disproportionate to the needs of the case, especially given the compressed schedule. Even before the Special Master broadened the scope of discovery, Purdue devoted more than 150 lawyers and other substantial resources to working nearly around the clock on discovery, producing nearly 20 million pages of documents. The Special Master's greatly expanded scope of discovery would impose an impossible burden on Purdue, as Purdue showed in its burden declaration, *see* Ex. 11, Hoff Decl., but the Special Master in Ruling No. 3 did not afford any consideration to Purdue's submissions, contrary to Fed. R. Civ. P. 26(b), which requires the Court to give the burden and proportionality of discovery as much weight as its relevance.

[5] Moreover, Plaintiffs continue to demand that the Teva Defendants collect and produce custodial email for new witnesses.

With respect to time scope, Purdue had already taken a broad scope of discovery and for many document categories has not limited the time scope of its production. For instance, Purdue's productions from its prior civil litigation against government entities contain documents going back to the 1980s. Nor did Purdue limit the time scope of other production categories, such as branded marketing, sales training material, sales call notes, and prescription data. Other document categories posed an unreasonable burden on Purdue to expand discovery beyond 2006, notably custodial file documents. Every year of additional custodial file discovery adds voluminous documents for attorney review, while the relevance becomes more and more attenuated going back in time. As Purdue showed in its burden declaration, the Special Master's Ruling No. 3 could inject millions of additional documents into Purdue's attorney-review pool, rendering it impossible to satisfy under the schedule. The Special Master erred in failing to give due weight to the burden consideration, as required by Rule 26(b). The time scope of that ruling, therefore, should be modified for Purdue to limit the temporal scope to 2006.

So, too, the Special Master's ruling on the scope of products should be modified. Plaintiffs focus their allegations against Purdue on OxyContin, and Purdue thus focused its discovery on the same medication. In the spirit of good faith and compromise, Purdue agreed (at substantial cost) to expand discovery to abuse-deterrent reformulation of OxyContin, Butrans, and Hysingla. Yet, the Special Master appears to have greatly expanded the scope of discovery to include nearly all of Purdue's branded products over a 23-year period. In doing so, the Special Master in Ruling No. 3 gave no consideration to Purdue's compromise and no apparent weight to the incredible burden of this expansion of discovery. Purdue showed in its burden declaration that this expanded scope would be impossible to apply, much less in the narrow time allowed for discovery. The ruling

should thus be revised to bound discovery by the four opioid medications Purdue has expanded its discovery to include: OxyContin, abuse-deterrent OxyContin, Butrans, and Hysingla.

Janssen Pharmaceuticals, Inc. and Johnson & Johnson Defendants ("Janssen"). Plaintiffs' twice-amended, 331-page complaint alleges that three Janssen opioids contributed to the current opioid-abuse crisis: 1) a short-acting, immediate-release tapentadol pill, Nucynta, 2) a long-acting extended-release tapentadol pill, Nucynta ER, and 3) a 72-hour fentanyl transdermal patch, Duragesic. Within the complaint, Plaintiffs devoted 20 paragraphs to discuss Janssen's opioid marketing practices for these three opioids. In all of these paragraphs, Plaintiffs *never* alluded to another Janssen opioid. As a result, Janssen structured its document collection and review on these clear representations that this case is about three Janssen opioids. Now, with a month left in fact discovery and Janssen already substantially completing its document productions of 50 custodians and 35 non-custodian sources, Janssen must expand its investigation, collection, and review to a 34-year-old, discontinued combination opioid for the treatment of acute pain, Tylox.[6] *See* Ex. 12, Decl. of V. Masson at ¶ 5.

Given the late addition of a discontinued product from the 1980s, Janssen is still in the early stages of its investigation into potentially responsive materials. Nevertheless, nearly all relevant documents would be in hardcopy form and will need to be located from warehouse storage. *See id*. at ¶¶ 7-9, 10. As a result, the time and expense needed to respond adequately to any discovery request for Tylox far exceeds the relevance to this case, which is trivial given Plaintiffs failure to even *name* the product in the 331 pages within their complaint devoted to other opioid products. While adding a new product this late in discovery is monumental, the temporal

[6] The FDA approved Tylox in 1984 and the product entered the generic market in the mid-1990s. On information and belief, Janssen stopped marketing Tylox shortly after it became generic, at which time Plaintiffs allege that Defendants' fraudulent marketing practices *began*. Janssen discontinued Tylox in 2012 after the FDA changed dosing limits on Tylenol, which was a non-opioid component of Tylox.

scope ordered by Special Master Cohen is particularly challenging. Under the current ruling, Janssen will have to conduct an entirely new review of hard copy documents dating back to 1995 for both Tylox and Duragesic (which was launched in 1989). This is not a case of simply applying additional search terms to a new custodian's emails and hard drives. Janssen must now search for 23-year-old paper files that discussed marketing, sales representative activities, regulatory interactions, educational activities, scientific research, convert those files into electronic form, and then review each page. Janssen cannot accomplish this task by the August 31 deadline. *See id*. at ¶¶ 10, 11.

Therefore, Janssen requests two modifications to Ruling Nos. 2 and 3. First, discovery should be limited to the three opioids named in the complaint: Nucynta, Nucynta ER, and Duragesic. If this Court believes that Plaintiffs should receive discovery on Tylox, it should be limited to keyword searches over Janssen's already selected "legacy drug portfolio" custodians. These custodians would have managed the Tylox product during its product cycle beginning in the late 1990s and early 2000s. Similarly, for Duragesic, Janssen has already produced its regulatory file, including the original NDA with marketing materials, from 1990, and has or will produce custodians who would have documents from the late 1990s, if not earlier.[7] Janssen should not be required to search through hardcopy documents dating back to 1995 for additional sources of information. This compromise targets the information requested by Plaintiffs in their argument to Special Master Cohen—"the baseline level of opioid prescriptions and distributions, which existed at that juncture [in 1995] . . . . " Ruling No. 2 at 9.

Endo Pharmaceuticals Inc. & Endo Health Solutions ("Endo"). The Track One complaints contain substantive allegations concerning Endo's promotion of a single opioid

[7] Janssen has never applied a date-range restriction on its document collection and review efforts.

medication, Opana ER, and opioids as a class. The allegations also relate to the distribution of opioids more generally, though none actually mention anything specific to Endo. Endo's June 12 submission to Special Master Cohen explained that the only relevant discovery concerning promotion is therefore that related to the promotion of Opana ER or opioids as a class. Endo also explained that, in an effort to compromise and in recognition of the generic distribution-related allegations, it agreed to provide distribution related discovery without an Opana ER-specific limitation. Without acknowledging this distinction, Ruling No. 2 expanded the scope of all discovery to any Schedule II opioid Endo has ever manufactured. More than a dozen products, some never mentioned in the Track One complaints, are now subject to broad discovery.

Compounding the burden of this expanded product scope is Ruling No. 2's temporal scope holdings, which is tied to the product scope ruling and effectively requires Endo to provide discovery spanning its entire existence, notwithstanding the lack of allegations about Endo conduct predating Opana ER. *See* Ex. 13, July 16, 2018 Guilds Decl. ¶ 14. Plaintiffs had agreed prior to Ruling No. 2 to a discovery date range for Endo starting in 2004, but now seek nearly a decade of additional discovery without any additional time for Endo to provide it. This is not possible given the current schedule and the time necessary to identify, collect, and process earlier materials, which include hardcopy, offsite documents or information in inactive systems. *Id.* ¶¶ 10-16. Simply identifying these materials is an enormous task given company turnover. *Id.* ¶ 14.

Even if the information called for by Ruling No. 2 was readily accessible, the resources to review and produce it would be substantial. Endo has already dedicated well in excess of 16,000 attorney hours to review and production, and has been required to open multiple review sites in different cities to produce what it had agreed to provide prior to Ruling No. 2. *Id.* ¶ 6-7. Completing that review by August 31 is "a monumental task." *Id.* ¶ 9. Neither the existing burden

on Endo to comply with the August 31 deadline nor the resources required to meet the temporal and product scope of Ruling No. 2 appears to have factored into any analysis of the appropriate scope of discovery from Endo. Ruling No. 2 also fails to address entirely the impact of the expanded product scope with respect to Endo's generics affiliates, Par Pharmaceutical Inc. and Par Pharmaceutical Companies, Inc. ("Par"). The Track One complaints are devoid of substantive allegations about Par, but a literal reading of Ruling No. 2 could require discovery into all aspects of Par's Schedule II opioid medications. This cannot be done by August 31. *Id.* ¶ 18.

A discovery time period tied to Opana ER's approval in 2006 is appropriate and proportional, as is a product scope focused on Opana ER and opioids as a class. Special Master Cohen's rulings on temporal scope should be modified to connect the time period for discovery to the claims as to Endo and his product scope ruling should be modified to reflect the Track One complaints' clear focus on the promotion of Opana ER and opioids as a class. Discovery as to distribution and sales figures for other opioids identified in the Track One complaints may be more proportional, but full scale discovery into those opioids is not.

CONCLUSION

The Manufacturer Defendants thus respectfully request that the Rulings be modified to the extent set out with respect to each Defendant in Appendix A.

Dated: July 24, 2018

Respectfully submitted,

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LOCAL RULE 7.1(F) CERTIFICATION

I certify that this Memorandum adheres to the page limitations set forth in L.R. 7.1(f).

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CERTIFICATE OF SERVICE

I hereby certify that on July 24, 2018, a copy of the foregoing **Manufacturer Defendants' Joint Objections to Discovery Rulings Nos. 2 and 3** and accompany exhibits was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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APPENDIX A

ALLERGAN PROPOSED PRODUCTION

Expanded Date Range	Allergan will agree to entirely remove the front-end date limitation from its review and production of collected documents and data. Put differently, Allergan will review and produce collected documents and data without any requirement that those documents or data be from after any date.
Expanded Opioid Products	Allergan will expand its production to include documents and data related to the other opioid medication that Allergan owns and has responsibility for that is identified in the Track One Complaints, Norco®.
Re-Review Already Collected Non-Custodial Sources	Allergan will review and produce, to the extent appropriate (*e.g.*, not privileged), documents and data that it has collected from noncustodial sources to date related to Norco®. Moreover, going forward, Allergan will collect Norco® related documents and data from noncustodial sources from which it is currently collecting or from which it agrees to collect in the future.
Additional Custodians	Allergan will add 12 additional document custodians associated with Legacy Watson (which owned Norco® prior to the combination of Legacy Actavis and Legacy Watson).
Additional Search Terms	Allergan will agree to add 93 search terms related to Norco®.

MALLINCKRODT PROPOSED PRODUCTION

Date Range	Mallinckrodt would produce responsive documents in the date range 2008-2017. This approach assumes that a reasonable agreement can be reached on the search terms to be applied.
Opioid Products	Mallinckrodt would expand its production to include documents and data related to all Schedule II opioid products identified in the Track One Complaints, a total of fifteen products, subject to the date range and search term restrictions described above.
Collection of Additional Non-Custodial Sources	Mallinckrodt would collect additional non-custodial data sources to expand the scope of its collection and production to include documents and data related to all Schedule II opioid products identified in the Track One Complaints, including the regulatory files and sales data for all Schedule II opioid products identified in the Track One Complaints. Mallinckrodt is assessing the availability of additional sources of data and the burden of collecting and reviewing them, including but not limited to suspicious order monitoring data for all of its Schedule II opioid products identified in the Track One Complaints.
Additional Custodians	Mallinckrodt has already agreed to add additional document custodians, including Ohio-specific custodians. Mallinckrodt would agree to add five additional custodians, subject to the date range and search term restrictions described above.
Additional Search Terms	Mallinckrodt has proposed that it incorporate the names and molecules of all its Schedule II opioid products identified in the Track One Complaints. Mallinckrodt has also already added 41 additional search terms at Plaintiffs' request. Mallinckrodt would agree to consider on a case by case basis any additional specific, targeted search terms proposed by Plaintiffs.

JANSSEN PROPOSED PRODUCTION

Date Range	Janssen has produced select regulatory documents going back to the original FDA approvals to capture early Duragesic marketing materials. Janssen's custodian collections will reach back to the late 1990s, and could easily extend farther as Janssen will not apply a date-range restriction.
Opioid Products	Janssen will produce documents related to Duragesic, the authorized generic fentanyl patch, Nucynta, and Nucynta ER.
Additional Custodians	Janssen has already added and will review an additional eight custodians to target pre-2000 documents about the marketing and promotion of Duragesic. These custodians are on top of 50 custodians and 35 non-custodian sources that resulted in the production of over 550,000 documents.
Additional Search Terms	Janssen has already proposed over 100 complex search strings averaging more than 40 terms per string, which were drafted by a third-party search consultant. Plaintiffs have yet to provide feedback on these search terms and Janssen will meet and confer with Plaintiffs on whether additional terms are necessary.

ENDO PROPOSED PRODUCTION

Expanded Date Range	Endo would agree to remove the front-end date limitation from its ongoing review and production of collected documents and data. Put differently, Endo will review and produce collected documents and data without a requirement that those documents or data be from after any date. For newly collected documents, Endo will assess the date range on a request by request basis.
Expanded Product Scope	Endo would expand its production to produce to Plaintiffs documents and data relating to any branded or generic Schedule II opioid medication that Endo has sold that are included in Endo's ongoing review and production of collected documents and data. Endo would also agree to collect additional non-custodial data to expand the scope of its existing collection to capture certain information about Schedule II opioids other than Opana ER. Specifically, Endo is identifying and collecting, to the extent not collected already, regulatory submissions files, promotional materials, and call data for branded and generic Schedule II opioids other than Opana ER that Endo has sold. Endo is evaluating the burden and feasibility of collecting adverse event data for its Schedule II opioids. With respect to Par, Endo would agree to produce sales and prescription data and suspicious order monitoring data for Schedule II opioid.
Additional Custodians	To the extent Endo identifies additional custodians with responsibility for Endo Schedule II opioids other than Opana ER, who are not duplicative of custodians on Endo's list already, Endo will add those custodians to its custodian list. Given the lack of specific allegations about the Par entities, Endo would not add Par custodians to its custodian list.
Additional Search Terms	Endo has agreed to add the brand and molecule name of its Schedule II opioids to the search terms it is running. To the extent Endo agrees to add additional search terms in the future, it will evaluate on a case-by-case basis whether the inclusion of terms concerning specific opioids other than Opana ER are appropriate.

PURDUE PROPOSED PRODUCTION

Date Range	Purdue would produce responsive documents in the date range 2006-2017. No date limitation was applied to New Drug Application files, branded marketing materials, sales representative call notes, and prescription data.
Opioid Products	Purdue would produce documents for OxyContin, abuse-deterrent reformulation of OxyContin, Butrans, and Hysingla. Purdue would include the names of its other opioid medications in search terms.

TEVA PROPOSED PRODUCTION

Date Range	Teva proposes modifying the Discovery Orders such that the relevant time frame for discovery is January 1, 2006 through 2017.
Custodians	Prior to the Discovery Rulings, Teva had already agreed to 34 custodians. With the Discovery Rulings, additional custodians are impracticable.
Search Terms	Prior to the Discovery Rulings, Teva had agreed to consider Plaintiffs' search terms. With the Discovery Rulings, Teva may not be able to complete its document collection, review and production by August 31 or prior to depositions, absent modification to Plaintiffs' search terms.
Prior Productions	With the Discovery Rulings, Teva may not be able to complete its collection and production of prior productions by August 31 or prior to depositions.